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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/517,605

12/21/2004

Yoshiji Yamada

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EXAMINER

HORLICK, KENNETH R

ART UNIT

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1637

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/517,605	Applicant(s) YAMADA ET AL.	
	Examiner Kenneth R. Horlick	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 2,3 and 5-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :12/21/04;11/1/05;2/22/06;3/28/08.

1. Applicant's election without traverse of Group I, claims 1 and 4, in the reply filed on 04/23/08 is acknowledged.

2. Claims 2, 3, and 5-12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 04/23/08.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed (i.e., detection of specific gene polymorphisms).

5. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
It does not identify the citizenship of each inventor.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Koch et al. (2001 Atherosclerosis).

These claims are drawn to methods comprising: analyzing two or more polymorphisms from a specific set of ten recited polymorphisms (claim 1), or such a method further comprising determining a genotype based on the detected polymorphisms, and assessing risk of myocardial infarction based on the genotype (claim 4).

Koch et al. teach a method comprising: analyzing the -819 and -592 interleukin-10 gene polymorphisms, as well as the -863 tumor necrosis factor α gene polymorphism, determining genotype, and assessing risk of myocardial infarction (see entire reference on pages 137-144).

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over any combination of two or more of: Boerma et al. (J. Int. Med. 1999), Skoog et al. (Human Mol. Genet. 1999), Inoue et al. (a) (Circulation 1998), Inoue et al. (b) (J. Clin. Inv. 1997), Lambert et al. (Human Mol. Genet. 2000), Yamada et al. (Metabolism 1998), Dammerman et al. (Proc. Natl. Acad. Sci. USA 1993), Topol et al. (Circulation 2001), or Koch et al. (2001 Atherosclerosis).

Each of these references teaches detection of at least one of the polymorphisms required in the claims as follows: Boerma et al. (position 1019 of the connexin 37 gene; see pages 211-218), Skoog et al. (position -863 of the tumor necrosis factor α gene; see pages 1443-1449), Inoue et al. (a) (position 242 of the NADH/NADPH oxidase p22 phox gene; see pages 135-137), Inoue et al. (b) (position -6 of the angiotensinogen gene; see pages 1786-1797), Lambert et al. (position -219 of the apolipoprotein E gene; see pages 57-61), Yamada et al. (position 994 of the platelet-activating factor

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acetylhydrolase gene; see pages 177-181), Dammerman et al. (position -482 of the apolipoprotein C-III gene; see pages 4562-4566), Topol et al. (position 1186 of the thrombospondin 4 gene; see pages 2641-2644), or Koch et al. (positions -819 and -592 of the interleukin-10 gene, and position -863 of the tumor necrosis factor α gene; see pages 137-144). Each of the references teaches that the noted polymorphism(s) are believed to be correlated with risk of myocardial infarction, or with another disease/condition associated with the cardiovascular system.

With the exception of certain specific embodiments as noted above in paragraph 6 with respect to Koch et al., none of the references teaches detecting more than one of the required polymorphisms.

One of ordinary skill in the art would have been motivated to detect at least two, and up to all ten, of the polymorphisms taught in any combination of two or more of the cited references because this would have provided the expected and predictable advantage of additive information regarding risk of a subject for myocardial infarction and other diseases/conditions associated with the cardiovascular system. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed methods.

8. No claims are free of the prior art.

9. The following are made of record as references of interest: DePhillipo et al. (US 2004/0005566), Cargill et al. (US 2005/0026169), and Cargill et al. (US 2007/0042382).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R. Horlick whose telephone number is 571-272-0784. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kenneth R Horlick/
Primary Examiner, Art Unit 1637

05/29/08